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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,742	12/29/2005	Kyoichi Shimomura	05832/HG	7803

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
01/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,742	SHIMOMURA ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-25* is/are pending in the application.

4a) Of the above claim(s) *10,12,14 and 16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13,15 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 10-25 are currently pending in the application.

Applicant's election of group II and election of compound C with traverse to various species in the reply filed on 10/16/08 is acknowledged. The traversal is on the ground(s) that the restriction requirement is not of the type set forth in MPEP 803.02 and is therefore not consistent therewith. This is not found persuasive because the instant application is in contrast to the MPEP which clearly states that in Markush type-claims, a restriction requirement is not required only if members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden. In the aforementioned instant, the examiner would then have to examine all the members of the Markush group in the claim on the merits. However, the Examiner contends that in the instant application, independent claim 1 recites a method of treating chronic pain utilizing any and every k-opioid receptor agonist. Consequently, such recitation would indeed be burdensome as a search for all κ-opioid receptor agonist will entail searching non-overlapping multiple databases for various references and literature searches. As a result, proper practice (i.e. according to M.P.E.P. 803.02 R-5) requires that in applications containing a Markush-type claim that encompasses at least two independent or distinct inventions,

the examiner may require a provisional election of a single species prior to examination on the merits.

Thus, the requirement is deemed proper and is therefore made FINAL.

Claims 10, 12, 14, and 16-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim. Claims 11, 13, 15, and 25 are examined on the merits herein.

Priority

Acknowledgment is made of applicant's claim for foreign priority. It is noted, however, that applicant has not provided English translations of the Japanese application as required by 35 U.S.C. 119(b). Nonetheless, the priority date of the instant invention is July 04, 2003. However, without the English translation, one cannot ascertain if the instant invention is present in the Japanese application. Therefore, art prior to the PCT date, but not before the date of the Japanese applications may be cited against the claims.

IDS

The information disclosure statement (IDS) submitted on 12/21/06 is acknowledged and has been entered. The submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the information disclosure statement has been considered by the examiner.

Drawing

The drawing, particularly figure 1, was received on 12/29/05. Accordingly, the drawing has been considered and entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13, 15, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In this application, the use of κ-opioid receptor agonists is critical or essential to the practice of the invention; however, applicant did not specifically describe all κ-opioid receptor agonists except the agonist derivatives of benzothiazoline. Consequently, due to this lack of written description, the

exact κ-opioid receptor agonists being claimed by applicant to be used in their method cannot be fully ascertained.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 13, 15, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4 and 6-7 of U.S. Patent 7,410,987 B2 (hereinafter Tokai US Patent No. '987). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of treating pain utilizing compounds of formula II. The claimed invention and U.S. Patent '987 are rendered obvious over another as the claimed invention teaches a subgenus of pain (i.e. chronic pain) using a subgenus compound of formula II (i.e. tartaric salt whereas Tokai '987 teaches a broad genus of pain using a broad genus of salts of formula II. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of U.S. Patent 7,410,987 B2.

Claim Rejections - 35 USC § 103

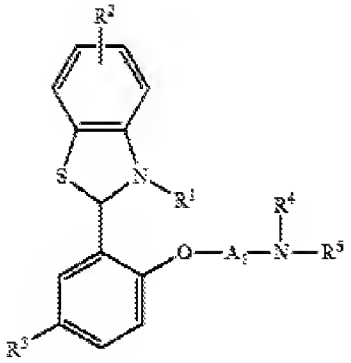
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 13, 15, and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Tokai et al. (U.S. 7,410,987 B2).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Tokai et al. teach a method of treating pain comprising administering to a patient in need thereof a pharmaceutically effective amount of a κ-opioid receptor agonist of the general formula III and salts thereof,



wherein R1 is acyl, R2 is halogen, R3 is an alkoxy group, R4 is an alkyl, R5 is A2R6, A1 and A2 are alkylene groups and R6 is an alkoxy group (see col. 3, lines 53-67 and col. 4, lines 1-12 and 21-54). Tokai et al. further teach compound C and salts of the invention including tartrate salts (applicant's elected species; see col. 6, lines 23-34 and col. 12, lines 1-20). Tokai et al. further teach the present compounds have excellent κ-opioid receptor agonist activities and antinociceptive actions and therefore may be useful as therapeutic agents of pain (see col. 76, lines 19-23).

Tokai et al. do not teach a method of treating chronic pain or continuous administration of the aforementioned compounds.

However, it is well within the purview of the skilled artisan to administer the aforementioned compounds for chronic pain give that Tokai teach the aforementioned compounds as therapeutic agents for pain and chronic pain is a type of pain. Moreover, given the nature of chronic pain which persists for an extended period of time, one of ordinary skill in the art would have found it obvious to administer the aforementioned compounds continuously in order to provide extended relief to patients suffering from chronic pain.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the compounds of Tokai et al. to treat chronic pain since Tokai teach the use of his compounds for pain and chronic pain is a type of pain. Moreover, one of ordinary skill in the art would have found it obvious to administer the method continuously since chronic pain persists for a long period of time and continuous administration would provide extended relief to such patients. Thus given the teachings of Tokai et al., one of ordinary skill would have been motivated to utilize the method of Tokai et al. to treat chronic pain with the reasonable expectation of providing a method that is efficient in treating chronic pain and effective in providing therapeutic relief to chronic pain sufferers.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

12/23/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617